JUL 17 2002

K020016

Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitters Information

Contact person: Thomas F. Flynn
Director of Regulatory Affairs

Address: Bayer Diagnostics Corp.
63 North Street
Medfield, MA 02052

Phone: 508 359-3877

Date Summary Prepared: February 21, 2002

2. Device Information

Proprietary Name: Bayer Rapidpoint 405 System

Common Name: Analyzer for hemoglobin and hemoglobin derivatives

Classification Name: Automated hemoglobin system

Classification Number: 21 CFR 864.5620, Class II

3. Predicate Device Information

Name	Rapidlab 800 Series Co-oximeter
Manufacturer	Bayer Corporation
510(k) Number	K946206

4. Device Description

The Rapidpoint 405 system Co-ox measurement cartridge measures the light from the whole blood at several wavelengths. The measurement cartridge detects and quantifies total hemoglobin (fractions and derivatives) and other related quantifies in the sample. Hemoglobin fractions and dervivatives are listed below:

tHb, FO_2Hb, FCOHb, FMetHb, FHHb

6. Summary of Technological Characteristics

The Rapidpoint 405 system Co-ox measurement module measures the light from the whole blood at several wavelengths. The measurement module detects and quantities total hemoglobin and other related quantities in the sample. It has the following components:

- The lamp (tungsten halogen)
- Lamp housing (lenses and filters)
- Fiber optic cables
- Wavelength calibrator (neon lamp)
- Photodiode feedback sensor
- Optics head assembly
- Sample chamber
- Polychromater

The lamp resides in a housing that contains a series of lenses and filters. Light from the lamp passes through these lenses and filters and is transmitted through a fiber optic cable. The light exiting the cable enters the optics head assembly, which directs the light through the sample chamber.

Before reaching the sample chamber, a portion of the light is diverted to a photodiode feedback sensor located on the main circuit board. The photodiode sensor provides electrical feedback to the lamp's control circuit to control the lamp's output intensity. The cable that connects the components of the measurement module is a multi-fiber bundle containing hundreds of fibers designed to deliver light that is uniformly distributed over the fiber face.

The sample chamber is located in the measurement cartridge. When the measurement cartridge is installed, the sample chamber is positioned between the two arms of the optics head assembly. The optics head assembly projects from the interface wall of the Rapidpoint 405 system. The arms are positioned on each side of the sample chamber. Mirrors and lenses in the optics head assembly focus and direct the light throughout the sample chamber for measurement and then on throughout the cable to the polychromater.

The sample chamber has a sliding cell design that opens and closes to allow for measurement and for the continued flow of the sample to the measurement sensor module. It also contains a thermister to control the temperature of the sample during measurement and a detector mechanism to sense the position of the chamber cell.

The polychromater separates the sample into its component wavelengths. It measures the intensity of light at the different wavelengths and converts the electrical signal to a digital value for further processing.

Additionally, the Co-ox measurement module has a wavelength calibrator that consists of a neon lamp, lenses and a filter. The neon lamp emits a stable emission spectrum that is used to test the alignment of the polychromater. Adjustments are made to maintain alignment of the polychromator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 17 2002

Mr. Thomas Flynn
Director, NPT & STS Regulatory Affairs
Bayer Diagnostics
63 North Street
Medfield, Massachusetts 02052-1688

Re: k020616
Trade/Device Name: Bayer Rapidpoint 405 System
Regulation Number: 21 CFR § 864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: II
Product Code: GKR
Dated: May 6, 2002
Received: May 8, 2002

Dear Mr. Flynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Bayer Rapidpoint 405 System

Indications for Use:

The Rapidpoint 405 System Co-ox measurement cartridge measures total hemoglobin and hemoglobin fractions and derivatives in arterial, venous and capillary whole blood samples. Hemoglobin fractions and derivatives are listed below:

Fractions:

tHb, FO_2Hb, FCOHb, FMetHb, FHHb

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

(Division Sign-Off)
Division of Clinical Laboratory Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) N K020616

Prescription Use ✓ OR Over-The-Counter Use _____